

REMARKS

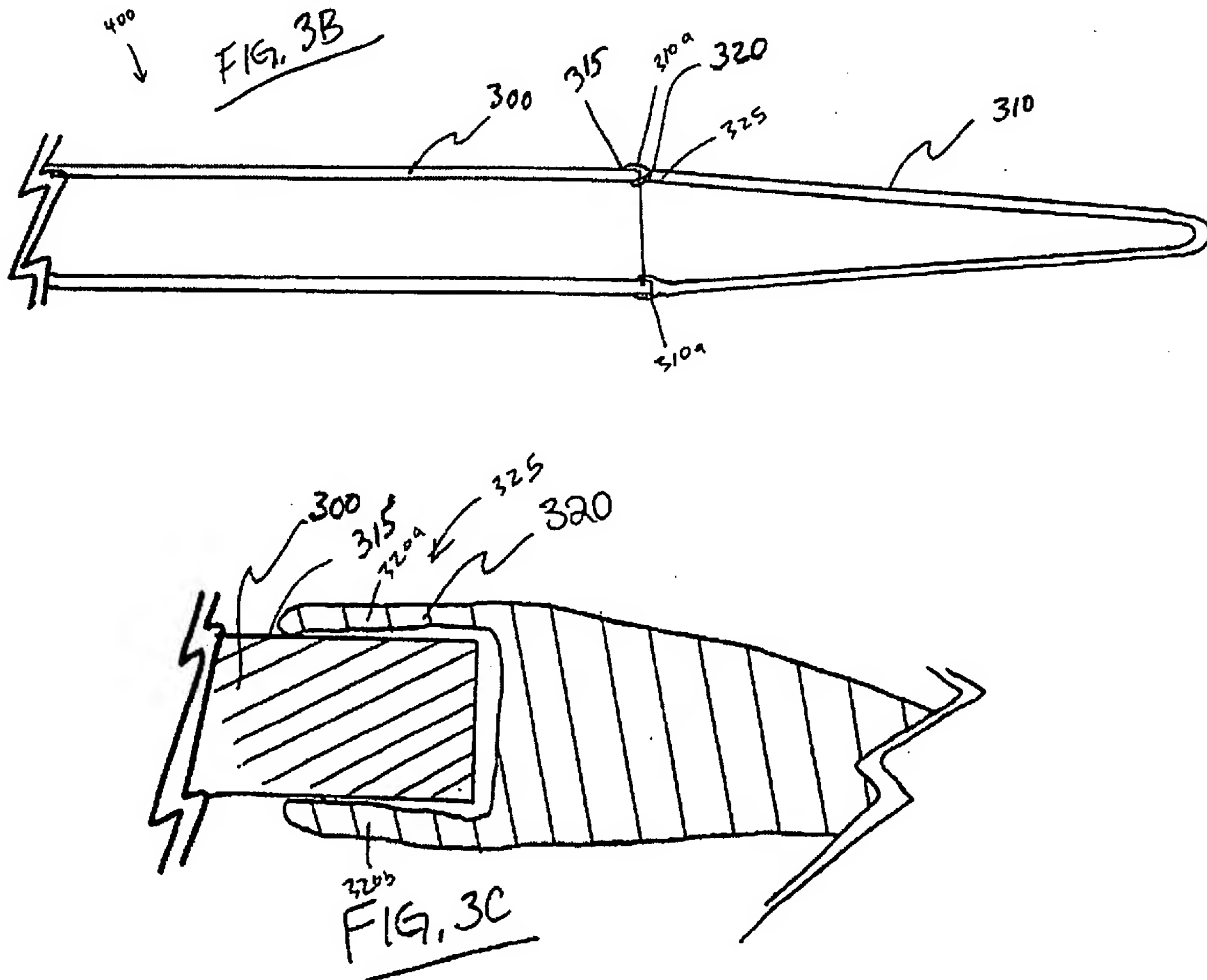
The above-identified application has been reviewed in light of the Final Office Action mailed on January 20, 2010. Claims 11-12, 15-20, 28, 31-33, 39-40 and 42-46 are currently pending. It is respectfully submitted that the pending claims are fully supported by the specification, introduce no new matter, and are patentable over the references of record. Reconsideration of the pending claims is earnestly requested.

In the Final Office Action, Claims 11, 12, 15, 16, 19 and 44-46 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,673,058 to Snow (hereinafter referred to as "Snow"). Applicant respectfully submits that independent Claim 11 is allowable over Snow.

According to § 2143.03 of the MPEP, "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." It is Applicant's position that all the words of the independent claims, as specified above, are not taught or suggested, either expressly or implicitly, by either of the above cited art.

Independent Claim 11 recites an orifice introducer device comprising, *inter alia*, a tubular member having a lumen and a distal end and a distal portion having a proximal end detachably connected to the tubular member, the proximal end having an annular groove that receives the distal end of the tubular member such that contact between the distal end of the tubular member and a side of the annular groove constrains the proximal end of the distal portion against radial contraction, wherein, when the distal portion is detached from the distal end of the tubular member, the proximal end of the distal portion

contracts from a radially outward position to a radially inward position such that the proximal portion has a smaller diameter than a diameter of the tubular member.



In an embodiment of the present application, as seen in FIGS. 3B and 3C (reproduced hereinabove), the proximal end 325 of the distal portion 310 is annularly shaped so as to be attachable to the distal end 315 of the tubular member 300. More specifically, as shown above in Figure 3B, the proximal end 325 of the distal portion 310 includes an annular groove 320 that is configured to receive the distal end 315 of the tubular member 300. (See Paragraph [0034] – [0035] of the present application).

Snow discloses the following:

FIG. 7B illustrates an alternate embodiment wherein the core of tip 16 is dissolvable and carries an outer ring 42 that is made of a thin non-dissolvable elastomere, such as silicone. This tip responds to natural or practitioner provided fluids to cause dissolving at the core. As the tip dissolves, outer ring 42 shrinks elastically until the interference fit between it and lumen 4 has been removed. When the interference is gone, the tip will fall out.

(See Snow at col. 8, lines 17-25)

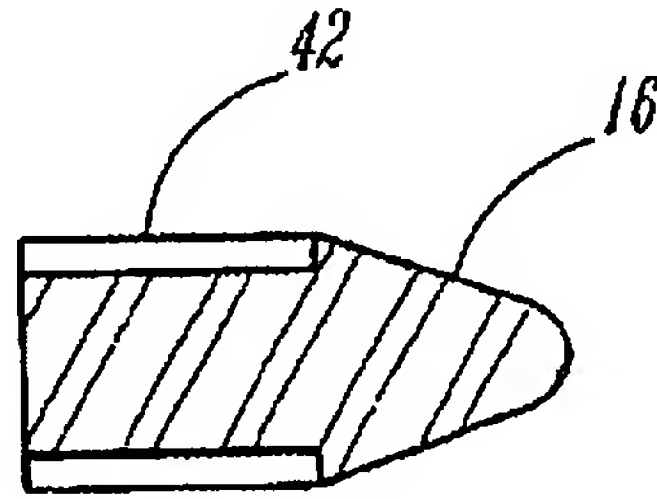


FIGURE 7B

On Page 2 of the Final Office Action, the Examiner asserts that the distal portion of Claim 11 is equivalent to the tip 16 of Snow. The Examiner further asserts that the proximal end of the distal portion of Claim 11 is equivalent to the outer ring 42 of Snow. Applicant respectfully disagrees with Examiner's assertions, since Claim 11 recites a single structure (e.g., a distal portion having a proximal end) and Snow clearly discloses more than one structure (e.g., a tip 16 and an outer ring 42).

On page 3 of the Final Office Action, the Examiner states the following:

Snow does not disclose that the proximal end having an annular groove that receives the distal end of the tubular member such that contact between the distal end of the tubular member and a side of the annular groove constrains the proximal end of the distal portion against radial contraction.

The Examiner goes on to state that "...Snow teaches another embodiment having grooves (Figs. 6c-6g) in order to secure a strong friction fit." The Examiner further states that it would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate protuberance on the embodiment of Fig. 7b to also insure a secure fit during use. The Applicant respectfully disagrees with the Examiner's aforementioned statements because it appears that the Examiner's conclusion of obviousness is based on improper hindsight reasoning. Assuming, for arguments sake, which Applicant does not contend, that Snow does disclose a distal portion in one embodiment and a groove in another embodiment, Snow still does not disclose, teach or even suggest a groove as recited in Claim 11. More specifically, Snow does not disclose a proximal end having an annular groove that receives the distal end of the tubular member such that contact between the distal end of the tubular member and a side of the annular groove constrains the proximal end of the distal portion against radial contraction.

After a careful review of Figs. 6c-6g, which the Examiner cited in the Final Office Action for teaching an annular groove, it becomes readily apparent that Snow does not disclose the annular groove, as recited by Claim 11. Thus, the Examiner has failed to

make a prima facie showing of “a side of the annular groove that constrains the proximal end of the distal portion against radial contraction.” Moreover, Snow does not even mention grooves; instead Snow discloses threads and protuberances that can not be equated to the limitations of Claim 11.

Further, Snow does not disclose, teach or suggest a distal portion that is detached from the distal end of the tubular member whereby the proximal end of the distal portion contracts from a radially outward position to a radially inward position such that the proximal portion has a smaller diameter than a diameter of the tubular member, as called for by Claim 11. In fact, even assuming, for arguments sake, that the outer ring 42 and the tip 16 are a single piece, which the Applicant does not contend, the outer ring 42 and the tip 16 of Snow are never disclosed and/or shown in a radially outward position. Rather, the outer ring 42 and the tip 16 of Snow are positioned in the lumen by an interference fit. In other words, the outer ring 42 and the tip 16 are fitted within the lumen. Thus, even if the outer ring 42 and the tip 16 included an annular groove, which the Applicant does not contend, it would be impossible for the outer ring 42 and the tip 16 to receive the distal end of the tubular member, since the outer ring 42 and the tip 16, as disclosed in Snow, fails to define any opening for receiving the distal end of the tubular member.

The Examiner solely relies on the knowledge acquired from the Applicant's disclosure to support the obviousness rejection. To read the important distinctions of Claim 11 into Snow and to frustrate the needs of the Applicant would be solely through hindsight recognition, which is clearly impermissible under USPTO guidelines. See

MPEP §2142 which prohibits the Examiner from applying hindsight based upon the Applicant's disclosure.

For at least the foregoing reasons, Applicant respectfully submits that Snow fails to suggest an orifice introducer device comprising, *inter alia*, "a distal portion having a proximal end detachably connected to the tubular member, the proximal end having an annular groove that receives the distal end of the tubular member," as substantially called for in Claim 11.

Since Claims 12, 15, 16, 19 and 44-46 depend, directly or indirectly, from Claim 11 and contain all the features of Claim 11, Applicant respectfully submits that for at least the reasons stated above for Claim 11, Claims 12, 15, 16, 19 and 44-46 are also allowable under 35 U.S.C. § 103(a) over Snow.

In the Final Office Action, Claims 11, 12, 15-19, 28, 31-33 and 44 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,176,127 to Dormia (hereinafter referred to as "Dormia") in view of U.S. Patent No. 6,332,877 to Michels (hereinafter referred to as "Michels"). Applicant respectfully submits that independent Claims 11 and 28 are allowable over Dormia in view of Michels.

Claim 28 recites a method for using an orifice introducer device comprising, *inter alia*, the steps of: providing a tubular member having a distal end; and detachably securing a proximal end of a distal portion to the distal end of the tubular member by receiving the distal end of the tubular member in an annular groove at the proximal end of the distal portion such that contact between the distal end of the tubular member and a

side of the annular groove constrains the proximal end of the distal portion against radial contraction, a distal end of the distal portion having a smaller diameter than the tubular member.

Dormia discloses, as shown in Figure 3, reproduced below, a mandrel head 9, a rod-shaped slide 10, and a jacket of an endoscope. Dormia further discloses that after inserting the endoscope with the spread-out mandrel head 9, the mandrel is pulled out after withdrawing the rod-shaped slide 10. This results in the elastic segments 16 springing back from their spread position into their initial position, utilizing their intrinsic elasticity. Afterwards, the tube 8 is disengaged from the jacket of the endoscope and the mandrel is pulled out. (See Dormia at col. 4, lines 51-60).

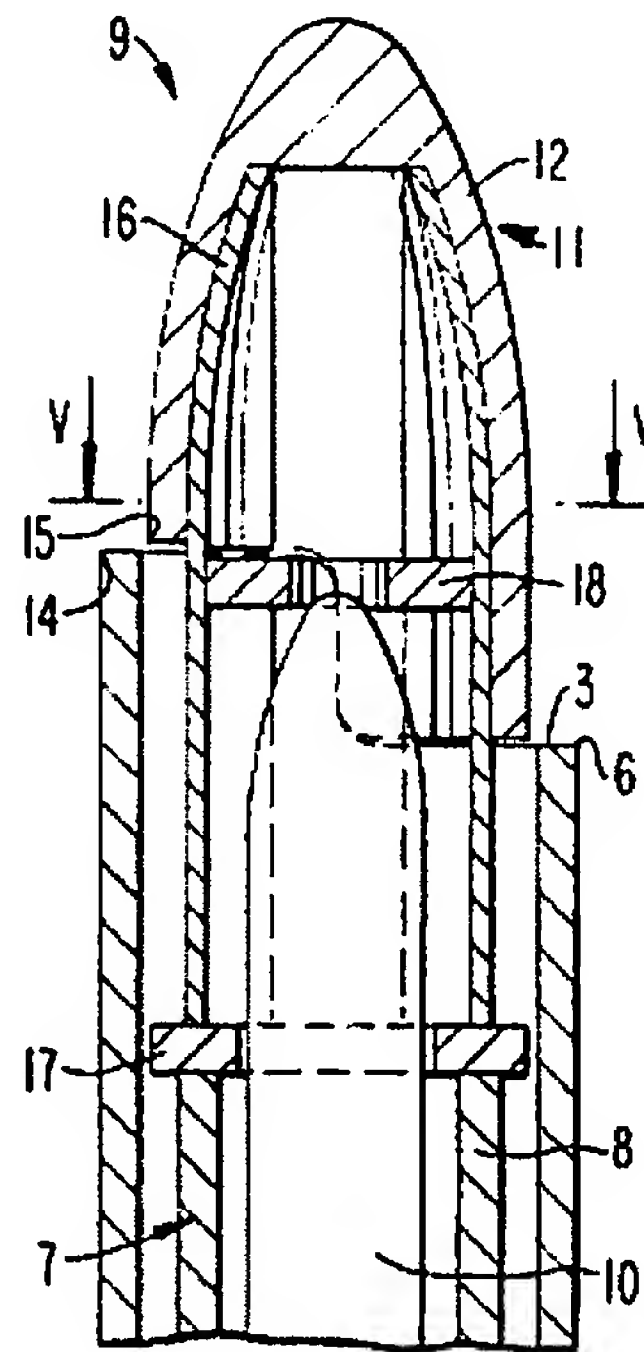
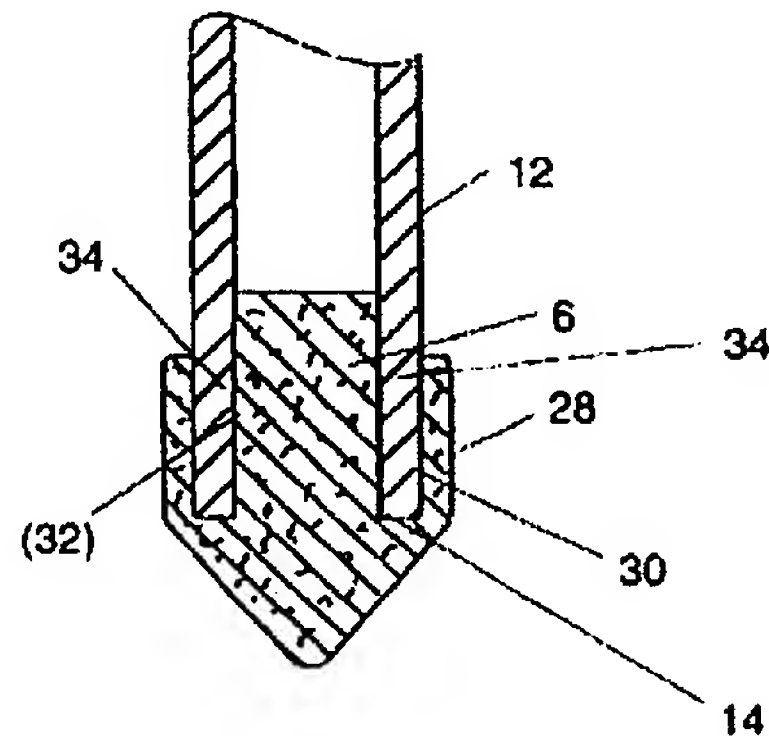


FIG. 3

Michels discloses body portion 6, as shown in Figure 6, reproduced below, that is designed to fit within the lumen of the tube 12, while the outer cylindrical skirt 28 fits over and surrounds the periphery of the tube 12. (See Michels at col. 6, lines 16-21).

Figure 6



On page 4 of the Final Office Action, the Examiner states the following:

Dormia does not disclose that the distal portion has an annular groove that receives the distal end of the tubular member such that contact between the distal end of the tubular member and a side of the annular groove constrains the proximal end of the distal portion against radial contraction. However, Michels disclose an insertion tube with a detachably connected tip.

Even assuming, for arguments sake, that Michels discloses a “tip” that has an annular groove, which the Applicant does not contend, the structural arrangement of the “tip” of Michels, as equated by the Examiner, includes a body portion 6 that fills the entire lumen of the tube 16. If the “tip” configuration of Michels’ was applied to the mandrel 9 of Dormia, the mandrel 9 of Dormia would not be able to spring back radially inward, since the body portion 6 would prevent such action. Thus, it is respectfully

submitted that the combination of Dormia and Michels does not render unpatentable Claims 11 and 28.

Since Claims 11, 12, 15-19 and 44 depend, directly or indirectly, from Claim 11 and contain all the features of Claim 11, and Claims 31-33 depend, directly or indirectly, from Claim 28, Applicant respectfully submits that for at least the reasons stated above for Claim 11 and 28, Claims 12, 15-19, 31-33 and 44 are also allowable under 35 U.S.C. § 103(a) over Dormia in view of Michels.

In the Final Office Action, Claims 20 and 39-43 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Dormia in view of U.S. Patent No. 6,042,538 to Puskas (hereinafter referred to as "Puskas"). Applicant respectfully submits that independent Claims 11 and 39 are allowable over Dormia in view of Puskas.

Claim 39 recites a device comprising, inter alia, a tubular member, a second member being arranged internally within the tubular member and being configured to move longitudinally relative to the tubular member; and a distal portion having a proximal end mounted to the distal end of the tubular member, the proximal end having an annular groove that receives the distal end of the tubular member such that contact between the distal end of the tubular member and a side of the annular groove constrains the proximal end of the distal portion against radial contraction, the distal portion being selectively detachable from the tubular member by engagement with the second member when the second member is moved distally longitudinally.

On page 4 of the Final Office Action, the Examiner states the following:

Dormia does not disclose that the distal portion has an annular groove that receives the distal end of the tubular member such that contact between the distal end of the tubular member and a side of the annular groove constrains the proximal end of the distal portion against radial contraction.

Since Claim 20 depends directly from Claim 11 and Claims 39-43 depend, directly or indirectly, from Claim 39, contains all the features of Claims 11 and 39, which includes having a distal portion that has an annular groove that receives the distal end of the tubular member such that contact between the distal end of the tubular member and a side of the annular groove constrains the proximal end of the distal portion against radial contraction and since Puskas does not cure the deficiencies of Dormia, as acknowledged by the Examiner, Claims 20 and 40-43 are also allowable under 35 U.S.C. § 103(a) over Dormia in view of Puskas.

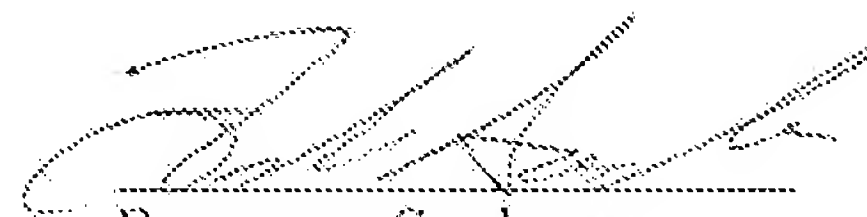
In view of the foregoing amendments and remarks, Applicant respectfully submits that Claims 1-26 are in condition for allowance.

Should the Examiner desire a telephonic interview to resolve any outstanding matters, the Examiner is sincerely invited to contact the undersigned at the number indicated below.

Application No. 10/632,271
Reply to Final Office Action dated January 20, 2010

An early and favorable response on the merits is earnestly solicited.

Respectfully submitted,



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